

### §315.3

### 16 CFR Ch. I (1–1–10 Edition)

*Contact lens fitting* means the process that begins after an initial eye examination for contact lenses and ends when a successful fit has been achieved or, in the case of a renewal prescription, ends when the prescriber determines that no change in the existing prescription is required, and such term may include:

- (1) An examination to determine lens specifications;
- (2) Except in the case of a renewal of a contact lens prescription, an initial evaluation of the fit of the contact lens on the eye; and
- (3) Medically necessary follow-up examinations.

*Contact lens prescription* means a prescription, issued in accordance with State and Federal law, that contains sufficient information for the complete and accurate filling of a prescription for contact lenses, including the following:

- (1) The name of the patient;
- (2) The date of examination;
- (3) The issue date and expiration date of prescription;
- (4) The name, postal address, telephone number, and facsimile telephone number of prescriber;
- (5) The power, material or manufacturer or both of the prescribed contact lens;
- (6) The base curve or appropriate designation of the prescribed contact lens;
- (7) The diameter, when appropriate, of the prescribed contact lens; and
- (8) In the case of a private label contact lens, the name of the manufacturer, trade name of the private label brand, and, if applicable, trade name of equivalent brand name.

*Direct communication* means completed communication by telephone, facsimile, or electronic mail.

*Issue date* means the date on which the patient receives a copy of the prescription at the completion of a contact lens fitting.

*Ophthalmic goods* are contact lenses, eyeglasses, or any component of eyeglasses.

*Ophthalmic services* are the measuring, fitting, and adjusting of ophthalmic goods subsequent to an eye examination.

*Prescriber* means, with respect to contact lens prescriptions, an ophthalmol-

ogist, optometrist, or other person permitted under State law to issue prescriptions for contact lenses in compliance with any applicable requirements established by the Food and Drug Administration. “Other person,” for purposes of this definition, includes a dispensing optician who is permitted under State law to issue prescriptions and who is authorized or permitted under State law to perform contact lens fitting services.

*Private label contact lenses* mean contact lenses that are sold under the label of a seller where the contact lenses are identical to lenses made by the same manufacturer but sold under the labels of other sellers.

#### §315.3 Availability of contact lens prescriptions to patients.

(a) *In general.* When a prescriber completes a contact lens fitting, the prescriber:

- (1) Whether or not requested by the patient, shall provide to the patient a copy of the contact lens prescription; and

- (2) Shall, as directed by any person designated to act on behalf of the patient, provide or verify the contact lens prescription by electronic or other means.

(b) *Limitations.* A prescriber may not:

- (1) Require the purchase of contact lenses from the prescriber or from another person as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section;

- (2) Require payment in addition to, or as part of, the fee for an eye examination, fitting, and evaluation as a condition of providing a copy of a prescription under paragraph (a)(1) or (a)(2) of this section or as a condition of verification of a prescription under paragraph (a)(2) of this section; or

- (3) Require the patient to sign a waiver or release as a condition of releasing or verifying a prescription under paragraph (a)(1) or (a)(2) of this section.